NATIONAL INSTITUTES OF HEALTH

ANIMAL STUDY PROPOSAL
(Revised 11/99)
(See NIH Manual 3040-2)

Leave Blank
PROPOSAL #
APPROVAL DATE
EXPIRATION DATE

PLEASE TYPE

A. ADMINISTRATIVE DATA:

Institute or Center _____

Principal Investigator _____

Building/Room _____ Telephone _____ FAX _____

Division, Laboratory, or Branch _____

Project Title _____

_____

_____

Initial Submission [ ] Renewal [ ] or Modification [ ] of Proposal Number _____

List the names of all individuals authorized to conduct procedures involving animals under this proposal and identify key personnel (i.e., Co-investigator(s)):

B. ANIMAL REQUIREMENTS:

Species _____ Age/Weight/Size _____ Sex _____

Stock or Strain _____

Source(s) _____ Holding Location(s) _____

Animal Procedure Location(s) _____

Number of Animals To Be Used

_____ , _____ , _____ = _____

Year 1 Year 2 Year 3 TOTAL

C. TRANSPORTATION: Transportation of animals must conform to all NIH and Facility guidelines/policies.
If animals will be transported between facilities, describe the methods and containment to be utilized. If animals will be transported within the Clinical Center, also include the route and elevator(s) to be utilized.

D. STUDY OBJECTIVES: Briefly explain in non-technical terms the aim of the study and why the study is important.

E. RATIONALE FOR ANIMAL USE: I) Explain your rationale for animal use. 2) Justify the appropriateness of the species selected. 3) Justify the number of animals to be used.
(Use additional sheets if necessary.)

F. DESCRIPTION OF EXPERIMENTAL DESIGN AND ANIMAL PROCEDURES: Briefly explain the experimental design and specify all animal procedures. This description should allow the ACUC to understand the experimental course of an animal from its entry into the experiment to the endpoint of the study. Specifically address the following:
(Use additional sheets if necessary.)

- Injections or Inoculations (substances, e.g., infectious agents, adjuvants, etc.; dose, sites, volume, route, and schedules)
- Blood Withdrawals (volume, frequency, withdrawal sites, and methodology)
- Non-Survival Surgical Procedures (Provide details of survival surgical procedures in Section G.)
- Radiation (dosage and schedule)
- Methods of Restraint (e.g., restraint chairs, collars, vests, harnesses, slings, etc.)
- Animal Identification Methods (e.g., ear tags, tattoos, collar, cage card, etc.)
- Other Procedures (e.g., survival studies, tail biopsies, etc.)
- Resultant Effects, if any, the animals are expected to experience (e.g., pain or distress, ascites production, etc.)
- Experimental Endpoint Criteria (i.e., tumor size, percentage body weight gain or loss, inability to eat or drink, behavioral abnormalities, clinical symptomatology, or signs of toxicity) must be specified when the administration of tumor cells, biologics, infectious agents, radiation or toxic chemicals are expected to cause significant symptomatology or are potentially lethal. List the criteria to be used to determine when euthanasia is to be performed. Death as an endpoint must always be scientifically justified.

G. SURVIVAL SURGERY - If proposed, complete the following:

1. Identify and describe the surgical procedure(s) to be performed. Include the aseptic methods to be utilized. (Use additional sheets if necessary):

2. Who will perform surgery and what are their qualifications and/or experience?

3. Where will surgery be performed? Building and Room? _____

4. Describe post-operative care required and identify the responsible individual:

5. Has major survival surgery been performed on any animal prior to being placed on this study? Y/N ___. If yes, please explain:

6. Will more than one major survival surgery be performed on an animal while on this study? Y/N ___. If yes, please justify:

H. PAIN OR DISTRESS CATEGORY - The ACUC is responsible for applying U.S. Government Principle IV. Contained in Appendix 3: "Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with sound scientific practices, is imperative. Unless contrary is established, investigators should consider that procedures that cause pain or distress in human beings may cause pain or distress in other animals." Check the appropriate category(ies) and indicate the approximate number of animals in each. Sum(s) should equal total from Section B.

IF ANIMALS ARE INDICATED IN COLUMN E, A SCIENTIFIC JUSTIFICATION IS REQUIRED TO EXPLAIN WHY THE USE OF ANESTHETICS, ANALGESICS, SEDATIVES OR TRANQUILIZERS DURING AND/OR FOLLOWING PAINFUL OR DISTRESSFUL PROCEDURES IS CONTRAINDICATED. PLEASE COMPLETE THE EXPLANATION FOR COLUMN E LISTINGS FORM AT THE END OF THIS DOCUMENT. THIS FORM WILL ACCOMPANY THE NIH ANNUAL REPORT TO THE USDA. NOTE: THIS COLUMN E FORM, AND ANY ATTACHMENTS, e.g., THE ASP, ARE SUBJECT TO THE FREEDOM OF INFORMATION ACT.

	NUMBER OF ANIMALS USED EACH YEAR		
	Year 1	Year 2	Year 3
[ ] USDA Column C - Minimal, Transient, or No Pain or Distress			
[ ] USDA Column D - Pain or Distress Relieved By Appropriate Measures			
[ ] USDA Column E - Unrelieved Pain or Distress			

Describe your consideration of alternatives to procedures listed for Column D and E that may cause more than momentary or slight pain or distress to the animals, and your determination that alternatives were not available. [Note: Principal investigators must certify in paragraph N.5. that no valid alternative was identified to any described procedures which may cause more than momentary pain or distress, whether it is relieved or not.] Delineate the methods and sources used in the search below. Data base references must include databases searched, the date of the search, period covered, and keywords used:

I. ANESTHESIA, ANALGESIA, TRANQUILIZATION - For animals indicated in Section H, Column D, specify the anesthetics, analgesics, sedatives or tranquilizers that are to be used. Include the name of the agent(s), the dosage, route and schedule of administration.

J. METHOD OF EUTHANASIA OR DISPOSITION OF ANIMALS AT END OF STUDY: Indicate the proposed method, and if a chemical agent is used, specify the dosage and route of administration. If method(s) of euthanasia include those not recommended by the AVMA Panel on Euthanasia, e.g., decapitation or cervical dislocation without anesthesia, provide scientific justification why such methods must be used. Indicate the method of carcass disposal if not as MPW.

K. HAZARDOUS AGENTS: Use of hazardous agents requires the approval of an IC safety specialist. Registration Documents for the use of recombinant DNA or potential human pathogens may be attached at the discretion of the ACUC.

	YES	NO	LIST AGENTS AND REGISTRATION DOCUMENT NUMBER (IF APPLICABLE)
1. Radionuclides			
2. Biological Agents			
3. Hazardous Chemicals or Drugs			
4. Recombinant DNA			

Study Conducted at Animal Biosafety Level: _____

Describe the practices and procedures required for the safe handling and disposal of contaminated animals and material associated with this study. Also describe methods for removal of radioactive waste and, if applicable, the monitoring of the radioactivity.

Additional safety considerations:

L. BIOLOGICAL MATERIAL/ANIMAL PRODUCTS FOR USE IN ANIMALS (e.g., cell lines, antiserum, etc.):

1. Specify Material _____
2. Source _____ Material Sterile or Attenuated? _____ Yes _____ No
3. If derived from rodents, has the material been MAP/RAP/HAP Tested? _____ Yes (Attach copy of results) _____ No
4. I certify that the MAP/RAP/HAP tested materials to be used have not been passed through rodent species outside of the animal facility in question and/or the material is derived from the original MAP tested sample. To the best of my knowledge the material remains uncontaminated with rodent pathogens.

   _____ Initials of Principal Investigator.

M. SPECIAL CONCERNS OR REQUIREMENTS OF THE STUDY - List any special housing, equipment, animal care (i.e., special caging, water, feed, or waste disposal, etc.).

N. PRINCIPAL INVESTIGATOR CERTIFICATIONS:

1. I certify that I have attended an approved NIH Investigator training course.

   Year of Course Attendance _____ Location _____

2. I certify that I have determined that the research proposed herein is not unnecessarily duplicative of previously reported research.
3. I certify that all individuals working on this proposal who have significant animal contact are participating in the NIH Animal Exposure Surveillance Program.
4. I certify that the individuals listed in Section A are authorized to conduct procedures involving animals under this proposal have attended the course "Using Animals in Intramural Research: Guidelines for Animal Users" and received training in the biology, handling, and care of this species; aseptic surgical methods and techniques (if necessary); the concept, availability, and use of research or testing methods that limit the use of animals or minimize distress; the proper use of anesthetics, analgesics, and tranquilizers (if necessary); procedures for reporting animal welfare concerns.
5. FOR ALL COLUMN D AND COLUMN E PROPOSALS (see section H): I certify that I have reviewed the pertinent scientific literature and the sources and/or databases as noted in paragraph H, and have found no valid alternative to any procedures described herein which may cause more than momentary pain or distress, whether it is relieved or not.
6. I will obtain approval from the ACUC before initiating any significant changes in this study.

Principal Investigator: Signature _____ Date _____

O. CONCURRENCES: PROPOSAL NUMBER _____ (LEAVE BLANK)

Laboratory/Branch Chief certification of review and approval on the basis of scientific merit. Scientific Director's signature required for proposals submitted by a Laboratory or Branch Chief.

Name _____ Signature _____ Date _____

Safety Representative certification of review and concurrence. (Required of all studies utilizing hazardous agents.)

Name _____ Signature _____ Date _____

Facility Manager certification of resource capability in the indicated facility to support the proposed study.

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

Facility _____ Name _____ Signature _____ Date _____

COMMENTS:

Facility Veterinarian certification of review.

Name _____ Signature _____ Date _____

Attending Veterinarian certification of review.

Name _____ Signature _____ Date _____

P. FINAL APPROVAL:

Certification of review and approval by the _____ Animal Care and Use Committee Chairperson.

CHAIRPERSON _____ Signature _____ Date _____